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Director-General,
Agri-Food and Veterinary Services

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ANIMALS AND BIRDS ACT

(CHAPTER 7)

ANIMALS AND BIRDS (CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES) RULES 2004

In exercise of the powers conferred by section 80 of the Animals and Birds Act, the Minister for National Development hereby makes the following Rules:

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ANIMALS AND BIRDS ACT

(CHAPTER 7)

ANIMALS AND BIRDS (CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES) RULES 2004

In exercise of the powers conferred by section 80 of the Animals and Birds Act, the Minister for National Development hereby makes the following Rules:

Citation and commencement

1. These Rules may be cited as the Animals and Birds (Care and Use of Animals for Scientific Purposes) Rules 2004 and shall come into operation on 15th November 2004.

Definitions

2. —(1) In these Rules, unless the context otherwise requires —

"animal" means any live vertebrate, including any fish, amphibian, reptile, bird and mammal but shall not include any human being;

"approved project" means any project that involves the use of any animal for any scientific purpose and that is approved by an institutional animal care and use committee;

"attending veterinarian" means a veterinarian employed by a licensee under rule 11;

"experiment" may consist of one or more separate procedures;

"guidelines" means guidelines issued or adopted by the Director-General under rule 18;

"institutional animal care and use committee" means a committee appointed by a licensee under rule 7;

"investigator" means a person who proposes, or is approved by an institutional animal care and use committee, to conduct an approved project;

"licence" means a licence issued by the Director-General under rule 4;

"licensee" means a person who holds a valid licence;

"personnel" , in relation to a research facility, means all the persons involved in the housing, feeding and general care or use of the animals, or who otherwise assist investigators, in the research facility;

"premises" includes the facilities, buildings, yards, paddocks, grounds and equipment therein;

"project" means an experiment or a series of related experiments that form a discrete piece of work or research for any scientific purpose;

"proposal" means a written outline of a project put forward for the consideration of an institutional animal care and use committee;

"research facility" , in relation to a licensee, means all the premises which belong to the licensee and which are approved by the Authority under the licence for the keeping or use of animals for scientific purposes;

"scientific purpose" means any purpose for which activities (including special breeding requirements integral to a research or teaching project) are performed to acquire, develop or demonstrate knowledge or techniques in any scientific discipline, including the purpose of research, teaching, diagnosis, field trials, product testing, production of biological products and environmental studies;

"veterinarian" means a person with qualifications in veterinary science who is licensed by the Director-General under section 53 of the Act.

(2) For the purposes of these Rules, a person shall be treated as keeping or using animals in his research

facility or premises for a scientific purpose if he allows any person to use his research facility or premises for such purpose.

Keeping or using animal for scientific purpose

3. No person, being the owner or occupier or having the management or control of any premises, shall keep or use, or allow any person to keep or use, any animal in those premises for any scientific purpose unless —

- (a) he holds a licence issued by the Director-General under these Rules authorising him to do so;
- (b) the keeping or use of any animal in those premises for any scientific purpose is carried out in accordance with the conditions of the licence;
- (c) the licensee has, in accordance with rule 7, appointed an institutional animal care and use committee and the project involving the keeping or use of the animal for the scientific purpose has been approved by the committee; and
- (d) the licensee has, in accordance with rule 11, employed an attending veterinarian.

Application for and issue of licence

4. —(1) An application for a licence shall be made to the Director-General in such form or manner as the Director-General may require and shall be accompanied by —

- (a) the appropriate fee as specified in the Schedule; and
- (b) such particulars, information and documents as may be specified by the Director-General.

(2) Subject to paragraphs (3) and (4), the Director-General may, on receipt of an application under paragraph (1) —

- (a) issue a licence to the applicant, whether unconditionally or subject to such conditions as he thinks fit to impose; or
- (b) refuse to issue any licence to the applicant.

(3) The Director-General shall not issue a licence to an applicant unless —

- (a) the applicant is —
 - (i) carrying on business in Singapore and is registered under the Business Registration Act (Cap. 32);
 - (ii) a company incorporated or registered under the Companies Act (Cap. 50);
 - (iii) a statutory body established by or under any written law; or
 - (iv) an institution of higher learning;
- (b) the functions or course of business of that person involves activities for scientific purposes; and
- (c) the Director-General is satisfied that the premises in respect of which the licence is being applied for are suitable for the keeping or use of animals for scientific purposes.

- (4) In determining whether to issue or refuse to issue a licence, the Director-General may consider —
- (a) the character and fitness of the applicant to be issued with a licence or, where the applicant is a body corporate, the character and fitness of the members of the board of directors or management committee or board of trustees or other governing body of the body corporate; and
 - (b) the ability of the applicant to operate and maintain the relevant premises in accordance with the requisite conditions and guidelines.
- (5) For the purposes of paragraph (3) (c), the Director-General may, at any time —
- (a) enter and inspect the premises in respect of which the application is made, or cause such premises to be inspected by an authorised officer; and
 - (b) require the applicant, at his own expense, to make such alteration or improvement to such premises or to provide, fix or install such facilities and equipment as the Director-General may specify.
- (6) The Director-General may refuse to issue a licence to an applicant if —
- (a) the applicant or one of his partners or, if the applicant is a body corporate, one of its directors —
 - (i) had previously been convicted of an offence under the Act; or
 - (ii) had previously held a licence issued under the Act and the licence was subsequently suspended or revoked under section 62 of the Act;
 - (b) in the opinion of the Director-General, the applicant —
 - (i) is not able to operate and maintain the relevant premises in accordance with the requisite conditions and guidelines; or
 - (ii) is otherwise not a fit and proper person to be issued a licence;
 - (c) in the opinion of the Director-General, the premises in respect of which the licence is being applied for are not suitable for the keeping or use of animals for scientific purposes;
 - (d) the applicant has not appointed, or has not undertaken to appoint, an institutional animal care and use committee in accordance with rule 7; or
 - (e) the applicant has not employed, or has not undertaken to employ, an attending veterinarian in accordance with rule 11.
- (7) The Director-General may, at any time, vary or revoke any of the conditions imposed under paragraph (2) (a) or impose new conditions.
- (8) Every licence issued under this rule —
- (a) shall be in such form as the Director-General may determine;
 - (b) shall be valid for the period stated therein unless it is revoked under section 62 of the Act; and
 - (c) may be renewed upon its expiry.

(9) Where the Director-General refuses to issue a licence under paragraph (2)(b), he shall, if requested to do so by the applicant, state in writing the reasons for his refusal.

(10) Paragraphs (1) to (9) shall apply, with the necessary modifications, to an application for the renewal of a licence.

Transfer of licence

5. No licensee shall transfer or assign the benefit of his or its licence to any other person.

Obligations of licensee

6. —(1) Every licensee shall ensure that the handling, care and treatment of any animal used for any scientific purpose in his or its research facility, including the transportation of such animal to and from the research facility, conforms to —

(a) the provisions of these Rules;

(b) the conditions of his or its licence issued under rule 4; and

(c) the relevant guidelines issued or adopted, and the relevant directives issued, by the Director-General under rule 18.

(2) Every licensee shall, within such time and in such manner as the Director-General may require, inform the Director-General of any change to the operations or personnel of his or its research facility.

Appointment and membership of institutional animal care and use committee

7. —(1) Every licensee shall appoint an institutional animal care and use committee in relation to his or its research facility.

(2) The appointment of an institutional animal care and use committee shall be made before the licensee keeps or uses any animal in his or its research facility for any scientific purpose.

(3) Subject to this rule, every institutional animal care and use committee appointed under paragraph (1) shall comprise at least 5 members, including one member from each of the following categories:

(a) a veterinarian with training or experience in laboratory animal science and medicine and who has experience in the routine care of the species of animals used in the research facility;

(b) a person with appropriate experience in the use of animals for scientific purposes;

(c) a person who —

(i) is not affiliated in any way with the licensee;

(ii) is not a member of the immediate family of any person who is affiliated with the licensee; and

(iii) is not a user of any animal for any scientific purpose; and

(d) a person whose primary concerns or interests are in non-scientific areas.

(4) Notwithstanding paragraph (3), no person shall be appointed as a member of an institutional animal care and use committee unless he is suitably qualified in accordance with such requirements as may be specified by the Director-General.

- (5) The attending veterinarian employed by a licensee under rule 11 shall be appointed as a member of the institutional animal care and use committee of the licensee.
- (6) The licensee or, where the licensee is a body corporate, the chief executive officer or other similar officer of the licensee, shall not be appointed as a member of the institutional animal care and use committee of the licensee.
- (7) The Chairman of the institutional animal care and use committee of a licensee shall be appointed by the licensee from amongst the members of the institutional animal care and use committee.
- (8) The licensee shall, before appointing any person as a member of an institutional animal care and use committee, notify the Director-General of the particulars of that person, including his name, address and occupation, the proposed date of his appointment, the term of his appointment and such other particulars as the Director-General may require.
- (9) The Director-General may at any time —
- (a) object to the appointment of a person as a member of an institutional animal care and use committee; or
 - (b) where the person is already a member of the institutional animal care and use committee, require the licensee who appointed that person as a member of the institutional animal care and use committee to remove that person from the committee and appoint another person in his place.
- (10) When any member of the institutional animal care and use committee appointed by a licensee ceases to hold office for any reason, the licensee shall notify the Director-General thereof within such time and in such manner as the Director-General may require.

Functions and duties of institutional animal care and use committee

8. —(1) With respect to activities involving animals in the research facility of a licensee, the functions and duties of the institutional animal care and use committee appointed by the licensee under rule 7 shall be as follows:

- (a) to review, at least once every 6 months, all programmes for the care and use of animals carried out in the research facility, using the guidelines as a basis of evaluation;
- (b) to inspect the research facility, including the housing facilities for animals, at least once annually, using the guidelines as a basis of evaluation;
- (c) to prepare reports of the evaluations conducted by the committee in accordance with such requirements as may be set out in the guidelines and submit the reports directly to the licensee;
- (d) to review and investigate any concern, complaint or report of non-compliance with any guideline involving the care and use of any animal at the research facility;
- (e) to make recommendations to the licensee regarding any aspect of the animal programme, facilities or personnel training at the research facility;
- (f) to review, approve, require modifications in, withhold approval of or reject any proposed project, or any proposed significant change in any ongoing project, relating to the use of any animal for any scientific purpose;
- (g) to withdraw approval for or suspend any project involving any animal if that project is not being

conducted in accordance with the guidelines or with the description thereof provided by the investigator and approved by the committee;

(h) to authorise the treatment or humane killing of any animal for any scientific purpose;

(i) to conduct continuing reviews of activities involving the use of any animal for any scientific purpose, including any approved project of long duration and any long-term continual use of any individual animal for such purpose, at appropriate intervals but at least once a year;

(j) to determine the best means of conducting an evaluation of the care and use of animals, provided that no member of the institutional animal care and use committee wishing to participate in any evaluation is excluded;

(k) to maintain a register of approved projects; and

(l) to perform all duties as required under the guidelines.

(2) An institutional animal care and use committee may invite ad hoc consultants to assist it in conducting an evaluation under paragraph (1) (a), except that the institutional animal care and use committee shall remain responsible for such evaluation and the report thereon.

Power of Director-General to order replacement of institutional animal care and use committee

9. —(1) Where the Director-General is of the opinion that the institutional animal care and use committee of a licensee is not discharging its functions in a proper or satisfactory manner, the Director-General may order the licensee to —

(a) remove or replace any member of the institutional animal care and use committee; or

(b) dissolve that institutional animal care and use committee and appoint a new institutional animal care and use committee in its place.

(2) Until the licensee has complied with any order given by the Director-General under paragraph (1) —

(a) the licensee shall ensure that no animal is kept or used by any person for any scientific purpose in the research facility of the licensee unless otherwise allowed by the Director-General and subject to such conditions as the Director-General may impose; and

(b) the Director-General may, if he thinks necessary, suspend the licence of the licensee.

(3) For the purposes of paragraph (1), an institutional animal care and use committee is not discharging its functions in a proper or satisfactory manner if the committee fails to comply with —

(a) any provision of these Rules; or

(b) any guidelines issued or adopted, or any directives issued, by the Director-General under rule 18.

Approval by institutional animal care and use committee of use of animal for scientific purpose

10. —(1) No person shall use any animal for any scientific purpose before written approval therefor is given by an institutional animal care and use committee.

(2) An institutional animal care and use committee shall not grant its approval for a proposed project or for any significant change to an ongoing project unless the committee is satisfied, upon conducting a review of the

components of the project, that the care and use of the animal will comply with the following requirements:

- (a) any procedure involving the animal will be carried out in a manner that will avoid or minimise discomfort, pain or distress caused to the animal;
 - (b) the investigator has considered alternatives to any procedure that may cause more than momentary or slight pain or distress to the animal and has provided a written and narrative description of the methods and sources used to determine that such alternatives are not available;
 - (c) the investigator has provided written assurance that the project does not unnecessarily duplicate previous experiments;
 - (d) the investigator has provided a justification for the endpoints of the experiments to be carried out in the project;
 - (e) the rationale for involving animals and the appropriateness of the species and the number of animals to be used justifies such use of the animals in the project;
 - (f) any procedure that may cause more than momentary or slight pain or distress to the animal —
 - (i) will be carried out in consultation with the attending veterinarian;
 - (ii) will not include the use of paralytics without anaesthesia; and
 - (iii) will be performed with appropriate sedatives, anaesthetics or analgesics, unless the withholding of such agents is justified for scientific reasons by the investigator in writing and will be continued for only the necessary period of time;
 - (g) the animal will undergo euthanasia as soon as possible if it experiences severe or chronic pain or distress that cannot be relieved;
 - (h) the personnel who will conduct procedures on the animal are appropriately qualified and trained in such procedures and any trainee involved in the conduct of such procedures will be under appropriate supervision;
 - (i) in the case of any project that involves surgery, appropriate pre-operative and post-operative care for the animal will be provided in accordance with established veterinary practices and all survival surgery will be performed using aseptic procedures and aseptic techniques;
 - (j) the animal will not be used in more than one experiment, unless the subsequent experiment is justified for scientific reasons by the investigator in writing and such repeated use of the animal complies with the guidelines; and
 - (k) the attending veterinarian is consulted on the use of appropriate euthanasia on the animal.
- (3) Any approval of a proposal granted by an institutional animal care and use committee shall not be valid unless the approval has been granted —
- (a) after a review of the proposal at a meeting of the committee consisting of the quorum and representation of the committee as required in the guidelines; and
 - (b) by the vote of a majority of the quorum at that meeting.

(4) An institutional animal care and use committee shall notify the relevant investigator and licensee in writing of —

- (a) any decision of the committee to approve or withhold approval of any project relating to the care and use of any animal for any scientific purpose; or
- (b) any modification to the proposed project required in order to secure the approval of the committee in respect of such project.

(5) If a member of an institutional animal care and use committee has any interest, directly or indirectly —

- (a) in any project the proposal for which is being reviewed or approved by the committee; or
- (b) in any other matter that can give rise to a conflict of interest on his part as such member in the review or approval of any project,

he shall disclose the nature of his interest at the meeting of the committee and shall not take part in any deliberation of the committee with respect to that project.

(6) If an institutional animal care and use committee suspends a project involving the use of any animal for any scientific purpose, the licensee shall, in consultation with the institutional animal care and use committee —

- (a) review the reasons for the suspension;
- (b) take appropriate corrective action; and
- (c) where directed to do so by the Director-General, report that action with a full explanation thereof to the Director-General.

Attending veterinarian and adequate veterinary care

11.—(1) Every licensee shall employ, on a full-time or part-time basis, an attending veterinarian with relevant training or experience in laboratory animal science and medicine to provide adequate veterinary care to the animals in the research facility of the licensee and shall comply with the following requirements:

- (a) the licensee shall arrange with the attending veterinarian to provide a written programme of veterinary care requirements to be complied with;
- (b) the licensee shall ensure that the attending veterinarian has appropriate authority to provide adequate veterinary care and to oversee the adequacy of other aspects of care and use of animals in the research facility; and
- (c) the attending veterinarian shall be a voting member of the relevant institutional animal care and use committee.

(2) The attending veterinarian shall be employed before the licensee keeps or uses any animal in his or its research facility for any scientific purpose.

(3) Every licensee shall, in respect of the animals in the research facility of the licensee, establish and maintain programmes of adequate veterinary care that are overseen by the attending veterinarian and that relate to —

- (a) the availability of appropriate facilities, personnel, equipment and services which comply with the relevant guidelines;

- (b) the use of appropriate methods to prevent, control, diagnose and treat diseases and injuries of the animals;
- (c) the availability of emergency, weekend and holiday care for the animals;
- (d) the daily observation of all the animals to assess their health and well-being;
- (e) the provision of guidance for investigators and other personnel on the handling of the animals, immobilisation, tranquilisation, anaesthesia, analgesia and euthanasia; and
- (f) the provision of adequate pre-procedural and post-procedural care for the animals in accordance with current established veterinary and nursing procedures.

Qualifications of personnel

12. —(1) Every licensee shall ensure that every investigator, member of an institutional animal care and use committee and all personnel involved in the care, treatment and use of animals in the research facility of the licensee for scientific purposes are suitably qualified, trained and instructed to perform their duties.

(2) Every licensee shall, with sufficient frequency —

- (a) provide the personnel involved in the care, treatment and use of animals with relevant training and instruction; and
- (b) review the qualifications of such personnel.

Keeping of records and reports

13. —(1) Every licensee shall maintain all records, reports and other documentation relating to the keeping and use of animals for scientific purposes in accordance with the guidelines.

(2) The licensee shall, at reasonable times, make all records, reports and other relevant documentation available for inspection and copying by the Director-General.

Annual report and information

14. Every licensee shall submit to the Director-General in such manner and as often as the Director-General may determine —

- (a) an annual report which complies with such requirements as may be set out in the guidelines; and
- (b) any other information as may be required by the Director-General.

Quarantine of animal

15. Every licensee shall ensure that the research facility of the licensee is equipped with suitable facilities for the quarantine of any animal, where necessary, upon the arrival of the animal at the research facility.

Licensee to report disease outbreak or unusual mortalities

16. Any licensee who has reason to believe or suspect that there is an outbreak of disease or unusual mortalities in his or its research facility shall immediately —

- (a) make a report thereof to the Director-General; and
- (b) cause the affected animals and all other animals in the research facility to be confined and isolated until further directions from the Director-General.

Animal not to be released without Director-General's permission

17. Every licensee shall ensure that no animal is released from his or its research facility without the permission of the Director-General if the licensee has reason to believe or suspect that the animal poses a risk of infection or disease to other animals or humans.

Guidelines and directives

18. —(1) The Director-General may issue or adopt such guidelines as he thinks fit for the purpose of providing guidance to licensees and institutional animal care and use committees on the standards, procedures and requirements for the care, keeping and use of animals for scientific purposes.

(2) The Director-General may, from time to time, issue to any licensee such written directives as he thinks necessary for the proper care, keeping and use of animals for scientific purposes and for the management and operation of the research facility of the licensee.

(3) Without prejudice to the generality of paragraphs (1) and (2), the guidelines and directives issued or adopted by the Director-General thereunder may provide for the following matters in respect of any research facility and the transportation of animals to and from such research facility:

- (a) the care, handling, restraint and treatment of animals;
- (b) the standards of housing, husbandry and living conditions of animals, including standards of bedding, sanitation, ventilation, feeding and watering;
- (c) the prevention, diagnosis, control and notification of animal diseases;
- (d) the provision of adequate veterinary care for the animals;
- (e) the monitoring of the well-being and health of animals and the prompt rectification of any deficiency in the conditions relating to the well-being and health of such animals;
- (f) the use of appropriate tranquilisers, anaesthetics, analgesics or sedatives on animals;
- (g) the practices in experimental procedures to minimise pain or distress caused to animals;
- (h) the provision of pre-surgical, surgical and post-surgical care for animals in accordance with established veterinary procedures;
- (i) the provision of emergency, after hour and special care measures for animals;
- (j) the identification, traceability and segregation of species and the breeding, procurement, supply, transportation, holding and release of animals;
- (k) the appropriate methods of euthanasia and the disposal of animals;
- (l) the qualifications, training and skills of personnel in the research facility;
- (m) the maintenance and submission of records, reports, forms and registers relating to the care and use of animals for scientific purposes;
- (n) the adoption of quality assurance programmes relating to the care and use of animals in the research facility; and

(o) the responsibilities of licensees, investigators, institutional animal care and use committees and personnel in the research facility.

(4) Where a licence is suspended or revoked under section 62 of the Act, the Director-General may issue to the person whose licence was suspended or revoked such written directives as he thinks necessary for the proper care and treatment of the animals in the premises and research facility to which the licence relates.

Offence and penalty

19. Any person or licensee who or which contravenes rule 3, 5, 6 (2), 9 (2) (a), 10 (1), 13 (1) or (2), 14, 15, 16 or 17 or fails to comply with any directive issued by the Director-General under rule 18 (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

Transitional provision

20. —(1) Notwithstanding the provisions of these Rules, any person who, immediately before 15th November 2004, had been keeping or using any animal for any scientific purpose in any premises shall be entitled to continue keeping or using animals for scientific purposes in those premises for a period of 2 months from that date, and if before the expiry of that period a licence is applied for under rule 4 in respect of those premises, he shall be entitled to continue keeping and using animals for scientific purposes in those premises until the date on which a licence under rule 4 is issued or the application for a licence under that rule is refused or withdrawn.

(2) Notwithstanding the provisions of these Rules, every person referred to in paragraph (1) shall be entitled to continue using the premises in respect of which a licence has been issued under rule 4 for keeping or using any animal for any scientific purpose —

(a) for a period of 6 months from 15th November 2004, without having appointed an institutional animal care and use committee in respect of those premises and notwithstanding that the project involving the keeping or use of the animal for the scientific purpose has not been approved and reviewed by such committee;

(b) for a period of 12 months from 15th November 2004, without having employed an attending veterinarian in respect of those premises;

(c) for a period of 18 months from 15th November 2004, without having to complete the required training as specified in the guidelines for all investigators and personnel in the care and use of animals for scientific purposes in those premises; and

(d) for a period of 18 months from 15th November 2004, without having to comply with provisions in the guidelines relating to infrastructure in respect of those premises.

THE SCHEDULE

Rule 4 (1) (a)

FEEES

Licence to keep and use animals for scientific purposes in any premises \$300 per annum.

Made this 25th day of October 2004.

TAN TEE HOW
Permanent Secretary,

*Ministry of National Development,
Singapore.*

[ND 311/13-225 Vol. 2; AG/LEG/SL/7/2002/1 Vol. 3]

(To be presented to Parliament under section 80 (4) of the Animals and Birds Act).

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